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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------|-------------|----------------------|---------------------|------------------|
| 10/068,553 | 02/06/2002 | Susan Cottrell | 81836 | 6966 |
| 7590 | 02/15/2005 | | EXAMINER | |
| KRIEGSMAN & KRIEGSMAN | | | WHISENANT, ETHAN C | |
| 665 Franklin Street | | | ART UNIT | PAPER NUMBER |
| Framingham, MA 01702 | | | 1634 | |

DATE MAILED: 02/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/068,553 | COTTRELL, SUSAN | |
| | Examiner | Art Unit | |
| | Ethan Whisenant, Ph.D. | 1634 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 22 NOV 04.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) 1-23 and 26 is/are allowed.

6) Claim(s) 24 and 25 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____.

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FINAL ACTION

1. The applicant's Responses (filed 26 MAR 03 and 22 NOV 04) to the Office Action(s) have been entered. Following the entry of the claim amendment(s), **Claim(s) 1-26** is/are pending. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

Note that the examiner in this application has changed. The examiner handling this application is now Ethan Whisenant (see below).

SEQUENCE RULES

2. This application now complies with the sequence rules and the sequences have been entered by the Scientific and Technical Information Center.

35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

or

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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4. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim Rejections under 35 USC § 102

5. **Claim(s) 24** is/are rejected under 35 U.S.C. 102(b) as being anticipated by Herman et al.(1996).

Claim 24 is drawn to a composition of pretreated genomic DNA according to any one of the preceding claims for the determination of the methylation status of a corresponding genomic DNA.

Herman et al. teach a composition of pretreated genomic DNA comprising all of the limitations recited in Claim 24.

35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

CLAIM REJECTIONS UNDER 35 USC § 103

7. The rejection of **Claim(s) 25** under 35 U.S.C. 103(a) as being unpatentable over Gonzalgo et al. (1997) in view of the Stratagene Catalog (1989) is maintained.

RESPONSE TO APPLICANT'S AMENDMENT/ ARGUMENTS

8. Applicant's arguments traversing the 103 rejection of Claim 25 over Gonzalgo et al. (1997) in view of the Stratagene Catalog (1989) have been fully and carefully considered but are not deemed to be persuasive.

To begin, the applicant traverses the 103 rejection of Claim 25 arguing that Gonzalgo et al. does not teach using their reagents as required by the method claims of the instant application. The examiner agrees with the applicants assertion that the claimed method(s) are distinct from that taught by Gonzalgo et al. However, the applicant in Claim 25 is claiming a product (i.e. a kit), and the intended use of said product does not further limit said product. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

The second argument that the applicant makes against the 103 rejection of Claim 25 is that there is no suggestion in the Stratagene catalog reference as to the desirability of assembling the particular items in question in kit form. The suggestion to assemble the reagents of Gonzalgo et al. into a kit arises from the teachings present the Stratagene Catalog wherein this references teaches the advantages of the kit format. "In actuality, the kit format saves money and resources for everyone by dramatically reducing waste." The examiner is not asserting that one would be motivated to perform the **claimed method** with the kit suggested by the combination of Gonzalgo et al. with the Stratagene catalog, rather, the as rejection makes clear that it would have been *prima facie* obvious to assemble the reagents disclosed by Gonzalgo et al. into a kit form in order to carry out the **method disclosed by Gonzalgo et al.** in the most cost efficient manner possible. Again, the intended use of the kit does not further limit the kit.

Conclusion

9. **Claim(s) 1-23 and 26** is/are allowable while **Claim(s) 24-25** is/are rejected and/or objected to for the reason(s) set forth above.

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10. Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Examiner is (703) 746-8465. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.



ETHAN WHISENANT
PRIMARY EXAMINER

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